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Issues and Options for the Multilateral Regulation of GM Foods

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As genetically modified food commodities have entered markets in recent years, domestic regulators have attempted to manage consumer, environmental and citizen concerns about these new products. One result has been incomplete and at times inconsistent domestic regulation, which has created international conflicts about market access. A number of international institutions have attempted in recent years to bridge the gulf between exporters and importers. This paper reviews recent international developments and offers options for different strategies for reducing the current tensions in international markets.

Keywords: biotechnology; international trade rules; negotiating strategies

Introduction

The trade policy system is now fully involved in handling disputes about trade in biotechnologically modified foods. While protests abound against it, production of the fruits of biotechnology has been increasing sharply. If one looks only at production of biotechnologically modified crops, James (1999) estimates that global production grew

from only a few acres in 1995 to approximately 100 million acres worldwide in 1999. With increased production comes the search for new markets. At the national level, biotechnologically advanced countries have grafted onto their existing regulatory frameworks new rules and institutions to handle specific concerns about biotechnology. The combination of incomplete and often conflicting domestic regulatory systems for biotechnologically modified products and increasing volumes of such products in international commerce has forced the regulation of products of biotechnology to spill over into the international sphere. At the international level, several institutions have modified their mandates to give them entry into the ring of biotechnology regulators. As with the national regulatory systems, conflicting perspectives about what and how to regulate abound. Suffice it to say that the current state of affairs at the international level is in a state of flux. While several mechanisms attempt to regulate parts of the problem, none provide a comprehensive base for managing the concerns related to newly crafted biotechnology organisms.

This piece sets out the parameters of what an international regulatory system must consider, which body or bodies might be best positioned to undertake such regulation, and the problems that any international attempts at co-ordination are likely to encounter.

A Précis of the International Institutions Currently Regulating Biotechnology

The biotechnology field is large and diverse and is changing frequently. Innovation and development have outpaced the development and implementation of an appropriate regulatory framework, both at the national and international level. There are currently seven international bodies active in fields affecting the co-ordination and regulation of products of biotechnology (Buckingham et al., 1999). Table 1 sets out in chronological order of establishment a summary of the international organisations actively involved in regulating products of biotechnology.

At the international level, regulatory bodies can be divided between two categories: those which are science- or health-based, and those with more broadly based objectives like facilitating international trade, examining environmental considerations, and arbitrating various other social and/or political goals. The first category includes organisations such as the International Office of Epizootics (OIE), the Food and Agriculture Organisation's International Plant Protection Convention (IPPC), and the joint FAO/World Health Organisation *Codex Alimentarius* Commission (Codex). The second category includes such organisations as the Organisation for Economic Co-operation and Development (OECD), the World Trade Organisation (WTO), the BioSafety Protocol (BSP), and various regional initiatives. Each of these institutions' current activities in the international regulation of biotechnology are set out in table 1.

Table 1 Current Array of Institutions Regulating International Trade in GM Crops

Institution	Estab.	Coverage	Member states	Dispute settlement	Orientation to products of biotechnology
International Office of Epizootics	1924	Pests and pathogens of animals and animal products	155	None; standards used by WTO	Creates international standards for animal measures involving quarantines and vaccines
GATT/ WTO	1947/ 1995	Trade in all goods and most services	137	Binding	Establishes rules for transparency and dispute settlement through TBT and SPS agreements
International Plant Protection Convention	1952	Pests and pathogens of plants and plant products	107	Non-binding; standards used by WTO	Creates international standards for plant measures involving quarantines
OECD	1961	Harmonisation of international regulatory requirements, standards and policies	29	None	Consensus documents for genetic composition of certain species; policy development
Codex Alimentarius Commission	1962	Development of food product composition, hygiene requirements and labelling of foods	165	None; standards used by WTO	Creates international standards for food, including composition and labelling
Regional initiatives (TEP; ECTI)	1990s	Harmonisation of the science of regulation	Bilateral	None	Regional side agreements, MOU, MRA, formal dialogues, and joint research
BioSafety Protocol	2000 (not yet in force)	Transboundary movements of living modified organisms (LMOs)	63 signed, 0 ratified (50 required)	None	Will require consent from importing state before transboundary movements of LMOs

Buckingham et al. (1999) offer an in-depth look at these institutions, concluding that there currently is not any one particular institution appropriately designed to regulate the vast array of aspects of products of biotechnology.

Recent Developments

Four recent developments have re-oriented the discussion of how biotechnology should be regulated.

First, in November 1999, nine intergovernmental organisations—the World Health Organisation (WHO), United Nations Conference Trade and Development (UNCTAD), WTO, OIE, FAO, Convention on Biological Diversity (CBD), UN International Development Organisation (UNIDO), OECD and the Consultative Group on International Agricultural Research (CGIAR)—got together for the first comprehensive dialogue on the international co-ordination of the regulation of biotechnology.[1] In May 2000, the group added the International Centre for Genetic Engineering and Biotechnology (ICGEB) and the United Nations Development Programme (UNDP) and adopted the name Inter-Agency Network for Safety in Biotechnology (IANB). This forum for dialogue and clearinghouse for information on the regulation of biotechnology is a welcome development upon the international stage.

Second, the riots in the streets of Seattle signalled an end to the private life of the WTO. Two items are particularly noteworthy about the "Battle for Seattle." First, the event galvanised civil society protests against multilateral organisations. The trend of "in-your-face" civil society involvement and protest will require international organisations to rethink how they operate, how they receive public input, and how they respond to public protest. While this may make for more transparent and democratic decision making in these institutions, the involvement of civil society could very likely distract intergovernmental organisations from their mandates and may drag some of them into areas where their expertise is limited and where they probably should not go. Civil society is not inclined at present to de-link analysis into trade issues, finance issues, labour issues, and equity issues, which will make it difficult to incorporate these areas of concern into the discussions of existing institutions. Further, Seattle highlighted the failure of member states to articulate and endorse a new agenda for WTO negotiations. The WTO has found that with 137 members it is hard to achieve consensus. There is some real fear, given the Seattle failure, that taking on too much could jeopardise the whole WTO structure. As a result, the WTO is now unlikely to lead the development of a negotiated solution for the regulation of trade in products of biotechnology. In response to the Seattle "speed bump" (Horlick, 2000), the WTO has tried to regroup on issues it can manage. It has begun the "built-in" agricultural negotiations and made an attempt at harmonising interpretations of the Sanitary and Phyto-sanitary Measures Agreement (SPS Agreement). Both actions point to a new realism at the WTO.

Third, the "Cartagena" Protocol on BioSafety was adopted by the Conference of the Parties to the Convention on Biological Diversity in January 2000 in Montreal. Since the adoption of the Protocol, 63 nations have signed the text but it will only come into force 90

days following the deposit of the fiftieth instrument of ratification. The Cartagena Protocol, when it comes into force, will create a new jurisdictional slice in the pie of international regulation of biotechnology. Special procedures will have to be followed for international shipments of living modified organisms (LMOs). Specifically, exporters will have to notify importing countries of any first-time transboundary shipments of LMOs intended for unconfined release. The importing country then will have the opportunity to undertake a scientifically based assessment of the risks those LMOs pose to the importing country.

Fourth, there have been renewed high-level international talks on biotechnology at the OECD, between the United States and the EU, and at the G8. Specifically, the OECD during 1999/2000 completed a formal review of national and international regulatory structures and held an international conference on food safety in Edinburgh in March 2000. Since then the OECD's work continues to highlight co-ordination, research and standards setting. In addition to their central role within the OECD, the United States and the European Union have separately and jointly undertaken new initiatives. Following efforts at domestic renewal, on 31 May 2000, the United States and Europe established a bilateral high-level discussion group to look at the risks and benefits of genetically engineered crops and foods (USDS, 2000). This Consultative Forum concluded in January 2001 with a list of relatively general observations about food safety, health and environmental concerns, the role of biotechnology in meeting food security needs of developing countries, and market access. The only recommendation that did not allow much wiggle room was that both countries should implement mandatory labelling rules. Now that the forum has reported its findings to the two governments it is not clear how the governments will respond. Meanwhile, the G8 Heads of State and Government continue to consider biotechnology and food safety.

Exploring the Options for Regulation

One challenge facing industry and governments is to determine what could be done at the international level to regulate biotechnology. We believe events over the past year have, without doubt, redefined the regulatory landscape. Two key conclusions are now starkly obvious. First, the biotechnology issue is not really one issue at all but a complex matrix of issues that touch on scientific, political, social, ethical and economic concerns. Second, it is highly unlikely that any international institution has the scope, the resilience, the political support, or the expertise to provide and support a comprehensive framework for the regulation of biotechnology. Both conclusions are perhaps self-evident but they produce important insights into what types of regulatory structures might or might not work. Food safety, trade, social, and environmental issues arising from biotechnology require significantly different analyses, involve different stakeholders and pose completely different deal-breaking problems.

We confidently conclude that the complexity of the various issues makes any comprehensive approach to the regulation of biotechnology next to impossible. Such an approach is also probably undesirable as comprehensive negotiations often lead to "horse-trading" that produces anomalies and inconsistencies (Kerr [forthcoming] notes, for example, the inconsistency of having intellectual property protection within the WTO). Furthermore, it is not clear whether there is any institution ready to accept such a gargantuan task. The OECD is facilitating dialogue and collecting data but suffers from a limited membership. The WTO has its hands full with other trade issues. The BioSafety Protocol has focused on environmental issues and will be fully occupied in its early years with establishing a framework for balancing international environmental interests without overly distorting international trade. Furthermore, consumer concerns and anxiety surrounding GM products coupled with the atmosphere of protest against large organisations demonstrate that comprehensive negotiations will be very difficult to sell to consumer and activist groups.

The alternatives to a comprehensive approach depend on the issues to be addressed. Public uneasiness about the development and exploitation of biotechnology coalesces around two basic questions—"is it safe?" and "is it good?" The question "is biotechnology safe?" leads to a discussion of how we can regulate biotechnology to protect human health and the environment. Most of the "hard law" of international regulatory agreements that have been concluded thus far has focused on this first question of whether biotechnology is safe. The work of the IPPC, the OIE, Codex, and the Consensus Documents of the OECD all have a primary focus of science-based empirical data to support a conclusion that a product or a species is safe for human consumption. Risk assessments completed within the regulatory scope of these bodies also go some way in providing scientific evidence to protect against more general threats to the environment. The question "is biotechnology good?" goes beyond matters of science, raising concerns about socio-economic interests and ethical boundaries for activities. The response to this question raises a whole slate of subsidiary questions. Should biotechnological inventions be protected and if so how? How will biotechnology affect the food security of developing countries? How will trade in the intellectual property and actual products of biotechnology affect competition, market concentration and investment opportunities?

These two questions bring into sharp focus the complexity of the regulatory task for national and international institutions in the area of biotechnology. Without a clear understanding of which question it is attempting to address, any institution will likely become confused, distracted and lose focus. Furthermore, the disciplinary approaches, the tools of analysis and the methodologies for solutions to the different questions will be different. Table 2 outlines some of the different dimensions for each question, placing the two major questions in the context of the methodological approach, disciplines, sources of informa-

Table 2 A Contextual Mapping of the Issues by Disciplinary Approach

Health and safety considerations		**Socio-economic considerations**
Scientific method	*Approach*	Principles, assumptions, axioms
Natural sciences, mathematics	*Disciplines*	Others (social sciences, humanities)
Collect data for proof	*Information sources*	Argue from principles to conclusions
From most certain result	*Conclusion*	From balancing dialogue, world view

The major questions placed in context

Food safety	Environmental safety	Equity and social concerns	Ethical concerns

tion and basis for making conclusions. While the conceptual mapping is a gross oversimplification of how the different basic questions are analysed, it is designed to establish the contention that the four major questions cannot be resolved with one approach. The different questions require different approaches.

Five specific approaches could be combined to begin to handle the wide array of concerns currently being expressed.

1. Encourage specialised institutions to develop expertise

In many ways, detailed and specialised scientific review has become the norm for the development of standards for biotechnology products. The OECD Consensus Documents demonstrate how progress can be made incrementally in the development of a regulatory scheme for crops. Industry standards (either brands or collective criteria as encompassed in the systems of the International Standards Organisation [ISO] or Hazard Analysis and Critical Control Point [HACCP]) can also provide a starting point for international standards. Standards from Codex, the OIE, and the IPPC could be used to build up a basic, agreed text of acceptable measures. Bilateral talks between major producer and major consumer nations will then be vital to arrive at a common standard, which could be put forward as an international standard for harmonisation. Harmonisation of risk assessment may in fact be illusory but the harmonisation of minimum standards and data requirements may be something that such processes could develop and then feed into the WTO.

While practical, this "patchwork" approach which defers to specialisation presents certain problems. Some issues are not immediately taken up by any institution (take for example the socio-economic issues). One of the biggest challenges of the current processes is that there is simply a lack of scientific data upon which to base new standards. Quintillan (1999), for example, argues that it is unclear how trade rules should respond to scientific uncertainty about the long-term effects on human health. Perhaps most difficult of all, this

approach depends on the negotiating countries having domestic regulations and systems. These are missing in many importing countries, which would limit this approach to the few nations with operating regulatory systems.

2. Developing the rules through the case law of the WTO and the IPPC

The processes for handling trade disputes are, for the most part, in place at the WTO. The benefit of this approach for countries exporting GM crops is that it would not require further negotiations and it would likely deliver pro-trade, science- and rules-based decisions. However, the case-by-case approach has some very serious drawbacks. Coverage of issues affecting biotechnology depends on cases actually being brought before the tribunals in question. The IPPC tribunal has heard no cases. WTO panels have heard cases on health and food safety issues but are ill equipped to deal with other questions such as how to balance environmental and socio-economic issues with trade concerns.

A number of other features, some practical and some systemic, make this approach problematic. First, there is the long-standing problem of unequal resources between developed and developing countries to bring a case (or several of them) before the WTO. Second, depending on the issues that member states would want to take forward to the dispute settlement system, it usually takes years to fully develop a body of law sufficient to regulate a sphere of activity as complex as trade in GM products. The international community may not be able to afford to wait that long. Finally, even when decisions are clear and complete, states do not always comply with the WTO's binding decisions (e.g., the EU has not complied with the panel ruling on the beef hormones case). At the end of the day, a losing party can side-step the consequences of a negative decision by paying compensation to the successful party. If such compensation is not forthcoming, the successful party can obtain an authorised suspension of trade benefits towards the losing party and enact trade sanctions. But in the end, the importing country's trade is not enhanced. Given the complexity and strongly held beliefs related to these cases, non-compliance is very possible, which could undermine the entire WTO system.

More fundamentally, the case-by-case approach can be attacked in that it is science-based and there is no institution that can develop a concurrent case law approach to deal with the outstanding socio-economic issues.

3. An industry-based model of regulation

One possible outcome of slow development of regulations might be for the companies or parts of the biotechnology industry to implement self-regulation to maintain market access. There are a number of cases where parts of the agri-food industry have developed systems to deliver products with higher standards than domestic or even international minimum standards. The red meats industry in Australia (Spriggs and Isaac, forthcoming), the canola industry in Canada (Gray, Malla and Phillips, 1999; Phillips and Smyth, 1999),

retailers and processors in the EU, North America, and Asia (Phillips and Foster, 2000), and the corn industry in the United States have all adopted private standards at one time or another in recent years. Over time, private standards, supplemented by HACCP protocols or ISO ratings (particularly 9000 and 14000 series) could supplement or replace public regulation. In order to address market demands, traceability and/or separability, new physical and organisational infrastructure may be required. Already the International Standards Organisation has developed new ISO eco-labeling standards (ISO 14020 and ISO 14024) and has presented industry with the opportunity to use the standards as a way to avoid environmental challenges to their products as they are introduced into domestic or foreign markets (ISO).

This approach is largely undeveloped at present but represents an interesting possibility for industry to avoid regulation by developing its own standards that will ensure consumer acceptance of their products. A major advantage is that such an approach would not require industry to bite off large chunks of the regulatory apple. Instead, problems can be resolved in bite-sized pieces as problems are identified.

This approach, however, could encounter some obstacles. First, it probably would depend on a general acceptance of the product, which is not currently present in many markets. Second, this approach requires collective institutions that are not yet in existence. These institutions could be commodity groups, trade associations, or new standards under the umbrella of one of the international standards organisations (Phillips, Henry and Porter, 2000).

4. Issues-based negotiations (bid/offer and MFN)

Perhaps it is time to go back into the past and adopt an old approach to this new technology. In the early rounds of GATT negotiations the process was predominantly one of reciprocal negotiating related to key issues and key markets. A country made bids and offers with key traders to liberalise specific areas; once bilateral agreements were set, they were multilateralised through the Most-Favoured-Nation principle. In this way the negotiations focused on those trade issues that had the greatest commercial importance. This strategy would entail the three countries producing and exporting the bulk of the GM crops—the United States, Argentina and Canada—engaging in narrowly based negotiations with the key importers—the EU and Japan—related to a handful of GM crops—soybeans, corn, cotton and canola. The strong reciprocity of interests in continued international trade in those products among those countries would improve the likelihood of success.

The main risks, which are not unique to this approach, are that issues-based negotiations tend to focus on older issues and not on breaking concerns and that trade distortions and disputes are likely. Furthermore, this approach will isolate many of the recently mobilised developing nations, which could put pressure on other forums.

5. A new forum for discussions

Currently, the IPPC, OIE and Codex handle health-related international discussions and the United Nations Environmental Programme handles international environmental issues, but no single agency (outside of the United Nations itself) has the scope to handle discussions related to international socio-economic issues. Some have suggested that a new body or international forum, like the Intergovernmental Panel on Climate Change (IPCC), is needed to handle the specific issue of the socio-economic implications of biotechnology (Krebs, 2000; May, 2000). It is unclear, however, what value such an institution would add to the international community's efforts to resolve the socio-economic questions. The fundamental problem is that while there are many socio-economic issues related to biotechnology, many (most) of them are not unique to biotechnology. Questions as to the rights of development, international and intergenerational equity, indigenous peoples' or farmers' rights, the impact of international agreements on farmers and consumers, and even ethical questions concerning the exploitation of life on the planet are not unique to biotechnology. Biotechnology may simply be a proxy issue for these larger problems rather than the real issue to be resolved.

Conclusions and Questions for Further Study

It is important to remember that the international regulatory system for biotechnologically modified products is continually evolving. The activities of the IPPC, the OIE, Codex, and to a lesser extent the Consensus Documents of the OECD are providing an elaborate system of scientific data to support the safe development and use of biotechnology. That body of scientific knowledge, particularly as it relates to food safety issues, then feeds into the WTO system through the SPS and TBT (Technical Barriers to Trade) agreements and is credibly able to enlighten panellists who must determine whether measures are protecting health in the least-trade-distorting way. The problem is that the non-scientific issues have no credible means of being heard and considered. Although some options exist, more thought is needed on how to handle these other issues.

Endnotes

1. For the complete report of the meeting, see "Report of a Consultation Meeting of Intergovernmental Organisations on Safety in Biotechnology", 25–26 November 1999 (available from Peter.Kearns@OECD.org).

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